EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

CARLOS A. GARCIA-PEREZ, et al.,

Plaintiffs,

v.

ALVARO SANTAELLA, MD, et al.,

Defendants.

Civil No. 97-1703 (JAG)

STATEMENT UNDER PENALTY OF PERJURY

I, Kenneth L. Harkavy, of legal age, married, and resident of Potomac, Maryland, hereby declare as follows:

1. I have been retained by plaintiffs in the above matter as an expert witness in the field of neonatology.

2. I was requested by plaintiffs to give my opinion in a written report as to the negligence of the defendants Ashford Presbyterian Community Hospital ("the Hospital") and Dr. Alvaro Santaella. My expert report dated August 9, 1999, complies with this request. It is my understanding based on information given to me by counsel for plaintiffs that Dr. Iván Terón Méndez was not a defendant in the action at that time, and for this reason my report does not mention any acts or omissions by Dr. Terón.

3. After my 1999 report was written, I was asked to evaluate the medical interventions of Dr. Terón in his care of the quadruplets. Based on the medical record of the

quadruplets at the hospital, my opinion is that Dr. Terón's acts and omissions pertaining to the care of Babies B and C deviated from the standard of care. Moreover, it is my opinion that Dr. Terón, who was a pediatrician and not a neonatologist and had only recently completed his residency, was not qualified to care for these quadruplets without direct supervision from a neonatologist. My opinion is based on the record of Dr. Terón's interventions, particularly the issues discussed below, as well as the added fact that the Hospital's neonatal intensive care unit was filled to capacity, as seen in the Hospital's daily census chart.

4. Regarding the care of Baby A, it is apparent from the record that Dr. Terón did not extubate or give the order to extubate the patient.

5. Regarding Baby B, Dr. Terón's treatment during his 24 hour shift from May 12 to May 13, 1996, in handling her low pH level was a deviation of the standard of care. Dr. Terón testified in his deposition that he was attempting to lower her respiratory rate in order to create an alkalosis. (See Day Two depo. tr. of Dr. Terón at pp. 20-21, **Exh. B**.) But looking at the actual gases in the chart, it is my opinion that he worsened the acidosis by compounding the metabolic acidosis with a respiratory acidosis. The baby's respiratory rate should not have been lowered until after the metabolic acidosis had been corrected. The prolonged acidosis (over 19 hours) likely caused multiple organ damage.

6. As to Baby C, she suffered from prolonged hyperoxemia, including during Dr. Terón's shifts, which resulted in her severe retinopathy of prematurity (ROP) and severe bronchopulmonary dysplasia ("BPD"). It is clear from the record that Dr. Terón ignored high oxygen saturation levels and permitted prolonged exposure to excessively high PaO2 levels during his shifts. Dr. Terón's deposition testimony admits that as the attending physician he was

responsible for the oxygen saturation level, although the nurses assisted in the monitoring. (Day One depo. tr. at pp. 63, 70-72, **Exh. A**.) He also testified that the monitor's alarm would be triggered only if the level went below 90, but there was no alarm if the level was too high. (Day Two depo. tr. at pp. 10-11, **Exh. B**.)

7. Another issue regarding Baby C was the level of PCO2. Dr. Terón testified that the acceptable levels for PCO2 was between 20 and 35 (Day One depo. tr. at pp. 65-66, **Exh. A**). These values are too low and the record shows that during Dr. Terón's shifts the levels were kept too low. The standard of care in 1996 was that PCO2 values were to be maintained above 35 torr and preferably above 40 torr. Dr. Terón's low levels contributed to Baby C's BPD and paraventricular leukomalacia, and were a deviation of the standard of care.

8. I did not testify and it is not my opinion that the baby's oxygen level is only the responsibility of the nurses. My opinion has always been that the standard of care is that it is ultimately the physician's responsibility to order and respond to in a timely fashion the blood gases and assure the proper oxygen levels.

9. As a final matter, I would like to clarify that it is my opinion that Dr. Terón is responsible for the care of the quadruplets during his shifts. The testimony that defendants refer to in their Statement of Uncontested Facts, paragraph 8, that Dr. Terón is not responsible for decisions made by the primary care neonatologist, is limited to the overall care plan and major decisions for the baby, not the routine care on the shift, such as maintaining proper oxygen levels and blood gas levels, as discussed above. Moreover, although Dr. Terón is not a neonatologist, he testified that he was the sole physician on duty during his shifts, i.e. unsupervised, and only called defendant Dr. Santaella when necessary for a consultation. (Day One depo. tr. at pp. 9-11, p. 24

(lines 23-25), p. 25 (lines 1-6), Exh. A.)

I declare under penalty of perjury that all the above is the truth to the best of my knowledge.

In Reston, Virginia, this 3rd day of February, 2005.

Kenneth L. Harkavy

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF PUERTO RICO

CARLOS A. GARCIA PEREZ,	–	
GISELA M. BAERGA TORRES,	–	CIVIL NO. 97-1703
et al.	–	
vs.	–	
ALVARO SANTAELLA, M.D.;	–	
NEONATHOLOGY GROUP OF	–	
ASHFORD PRESBYTERIAN	–	
COMMUNITY HOSPITAL,	–	
et al; ASHFORD PRESBYTERIAN	–	
COMMUNITY HOSPITAL, et al.	–	

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IVAN TERON

taken on March 22, 2002, at the offices of Nachman, Guillemard and Rebollo, located at the San José Building, Floor 9, Ponce de León, Santurce, Puerto Rico.

A I don't recall.

Q You were granted privileges to work at Ashford Hospital correct?

A Yes.

Q And, how does that happened?

A I gave my application for the privileges to doctor Santaella.

Q So that was the extend of your involvement on receiving the privileges?

A That is so.

Q When you were hired by doctor Santaella did he discuss supervision with you?

A What you mean in terms of supervision?

Q I mean, did he discuss the issue of whether or not you will be supervised while you were working at the NICU by another doctor?

A Well, he told me that I was to have a schedule from 4:00 in the afternoon to 12:00 midnight. And during that time any problem that would arise I could call him or the neonatologist on call.

Q And was any indication as to when or why you wanted to call him or another neonatologist?

A Only when a situation becomes complicated and I could not solve it.

Q Did he discuss with you the fact that you were not

a, or did he express any concerns that you are not a neonatologist but a pediatrician working at the NICU?

A No.

Q Did he discuss with you what your specific duties would be at Ashford's NICU?

A Well yes.

Q What did you discuss?

A That I was to be there and I was to take care of all the C-sections. All the complicated deliveries. Admit any baby that had any problems at the nursery area aside from following up on all of those who were already at the intensive unit.

Q In regards to following up the babies that were in the NICU unit was there any discussion with doctor Santaella as to what you could or what type of medical care you could or could not provide to those babies?

A As far as that goes I was there to follow up on the treatment that was already installed.

Q Installed by who?

A By the neonatologists.

Q So you were following a medical care plan that've already been put into place by another neonatologist.

A Yes.

Q Were you ever limited or did doctor Santaella ever limit you in terms of specifically in terms of things that

you could not do because you were not a neonatologist in the NICU?

A No.

Q Did you ever receive a written, oral verbal evaluation of your job performance by doctor Santaella?

A Well, doctor Santaella expressed verbally that he was quite pleased with my performance.

Q When are you referring to?

A There was not a specific moment.

Q Was it something he did coming into the NICU and tell you verbally that he was pleased with your performance?

A This was outside the Intensive Unit.

Q Was this in a meeting that you would have with him or when would this occur?

A Not this happened on an occasion that we meet at a restaurant in Caguas.

Q Do you recall when that was?

A No.

Q Was it shortly after you commenced work with him, two years later, do you know?

A I cannot specify.

Q Is that the only evaluation or comment that you recall that doctor Santaella made regarding your job performance?

A It is the only.

summary that have been prepared by doctor Quiñones?

A Yes.

Q Would you think that everything that was included in doctor Quiñones summary was also included in the progress notes?

A I can't say yes without a doubt, but most of it was.

Q Explain to me, let's say in May of 1996, you started your shift at 4:00 o'clock, what was the first thing that you'll do when you went into the unit?

A I came into the Nursery Unit which is the first door, the sinks were there. I would first take out some paper, then I would wash my hands, I will dry with that paper and I would close the keys with that paper and I would go through the second door which was the Intensive Unit and I will go with a paper rope on. There I would wait for whichever doctor was there to handle me shift.

Q And how this that happened, how was handled over the shift?

A It could be in two different manners. We would go in front of each patient one by one or at the desk I would receive the reports discussing each patient one by one.

Q Ok, and in May of 1996, was there another doctor usually on duty at the same time with you?

A With me present physically?

Q Yes?

A No.

Q So, once they handed the shift over you were responsible for the care of all the babies in the NICU at that time?

A Yes.

Q And, on what basis would you decide for instance which baby to take of first?

A Based on the reports, you would treat whichever was in the worst condition first.

Q When did you find out that these quadruplets were going to be delivered at Ashford Presbyterian?

A On the same day that they were born.

Q Do you know about what time, do you recall?

A I remember that I was leaving the hospital. I had been on shift on the day before. I was paged to please go to the nursery. When I come back to find out what happened I am told that quadruplets are going to be born. And I asked which because as I understood there was nothing on the delivery room. And that's when I found out.

Q And your shift was probably over about 8:00 a.m.?

A Yes.

Q And then what did you do once you found out that there were do to be born?

A I once again went to wear my rope in order to come

A I don't remember.

Q When you are on duty were you responsible during the time that the quadruplets were there, were you responsible for monitoring the baby's oxygen saturation levels?

A In the plans I was indicated to try and lower the ventilators parameters in order to lower the oxygen acceptable levels.

Q And, where again is this plan?

A In the reports I received from the days shift.

MS. JOAN PETERS: I'm going to show you, this is an arterial blood gas chart regarding Baby C, I'm going to actually mark it as an exhibit because I cannot, this was giving to us in the first production of documents and it was not, at least I cannot find it in the record that was subsequently given to all parties and numbered.

(EXHIBIT NUMBER 1 OF THE DEPOSITION IS MARKED)

BY MS. JOAN PETERS:

Q Ok, looking at this chart, and you had previously establish that you were on duty May 7th from 4:00 p.m. to 8:00 a.m. the 8th. So, can we start by looking the first entry that would've been during your shift. And, can you tell me, that would be at 6:10 p.m., correct?

A Yes.

Q Ok, can you look at those entries and tell me if any of those readings are normal or abnormal?

Q Ok, and that directly affects the PO2?

A Yes.

Q Ok, continuing down through your shift, can you tell me when the PO2 level reached an acceptable level?

MR. JOSE HECTOR VIVAS: Objection as to the form.

A On the 6:00 in the morning gases.

Q Ok, and there you have the PO2 of 105?

A Yes.

Q What about the other entries of the 6:00 a.m. time, where they also acceptable to you?

A What other entries?

Q Ok, the PH levels?

A 7.40, yes. CO2 was 25 and that was Ok. Bicarbonate was 19 and although this is not normal it is not corrected, it leaves as it is. 97.9% of oxygen saturation, that is Ok.

Q Ok, the PCO2 is indicated at 25, what do you consider to be an acceptable level of PCO2?

A According to what I learned in my residency, it should not be allowed to go under 20.

Q So, anything over 20 was acceptable to you?

A Not any number.

Q Up until what number?

A Approximately 35.

Q Ok, so the PCO2 is between 20 and 35 and is acceptable to you?

A Yes.

Q What was the acceptable level, what do you think the acceptable level was for the PO2?

A Between 60 and a 100.

Q My understanding is that your next shift was on May 8 from 4:00 p.m. to 12:00 midnight? If you would like to verify that with the record, you can.

A I see here the gases written by me on those hours.

Q And, what entries are those?

A 7:30 p.m.

Q Ok, looking at the 7:30 p.m. entry, what is the PO2 level?

A 319.

Q So, that was not acceptable to you?

A Is not acceptable.

Q What about the next entry for PO2?

A 10:30 in the evening.

Q And, what was the PO2 level?

A 273.

Q What were you doing to lower the PO2 levels?

A At 7:30 p.m. I started lowering the FIO2 in order to take it to 60 percent. At 10:30 p.m. I also lowered the FIO2's slowly this time in order to take it down to 50 percent.

Q And, were you successful in lowering the PO2?

A I presented the patient's case and he decided.

Q Do you know whether, in regards to the care of Baby A, B, C or D, did you ever prescribe an antibiotic without a neonatologist's decision or approval?

A I don't remember doing that.

Q The decision to discontinue the rocefin would that've been your decision or that of the neonatologist?

A Neonatologists are the ones to decide which medication to discontinue.

Q I want to go back to the issue about oxygen saturation because I have a few doubts that I wanted to ask you about so I'm going to give you again Exhibit 1. What involvement did the nurses at the NICU Unit have with the monitoring of the oxygen saturation levels?

A Regarding the oxymeter machine or the ventilator?

Q Both?

A Regarding ventilators they have nothing to do. Regarding the oxymeter they maintain the alarm level so that it goes on when the level goes under 90.

MR. ROBERTO RUIZ COMAS: I think it's that the alarm sounds when the oxymeter levels go below 90.

A And, also maintain the electrolytes well adjusted in the baby.

Q You stated that the alarm rings when the levels goes under 90, what is that 90 referring to?

A Oxygen saturation.

Q Ok, so, the nurses are not monitoring for instance the PCO2 levels or PO2 levels or anything of that?

A No.

Q If the alarm went off, if the alarm sounded when the level went under 90, what was the nurse aloud to or was suppose to do at that point?

A The first thing they did was to check the baby.

Q And then?

A If it was a matter of the electrolyte falling out they will put it back. It was a matter of the baby moving a lot, which is something that sometimes happens, the alarm would stop ringing. If the baby moves too much it could make the alarm go off and ring and then it would saturate again and stop. If they saw that what was happening was that the baby was changing colors, the baby's skin was changing colors then they would call me.

Q Did they have permission, did the nurses have permission to wind the FIO2 level?

A I don't know whether they had the permission or not. In my shift I did it.

Q Do you mean that during your shift do you expressly told them not to do that?

A No. They knew I did it.

Q Regarding the babies oxygen saturation levels, was

there an overall policy or plan by the primary physician that was communicated to you?

A The policy was to try to wind the patient from the ventilator as much as the patient would tolerate.

Q But doctor Casado for instance would leave you instructions as to how to attain that role?

A No.

Q What about the PH level that is indicated on the material blood cast chart, what would be an acceptable range of PH?

A From 7.35 to 7.45.

Q What did you do to maintain that level?

A It depends on the situation. If it was under 7.35 one would have to check if the patient was on metabolic acidosis and whether bicarbonate could be administered or if whether the patient had to much CO2 in the blood and then one would go to the ventilator an increase the respiratory rate and with one of those two ways the PH level could be fixed. If on the other hand the PH level was over 7.45 it could be that the CO2 was to low and there one could lower the respiratory rate on the mechanical ventilator so that he will keep CO2 and the PH level would lower.

Q Ok, and looking at your entry from your shift on 5/7 from 4:00 p.m. to 8:00 a.m., what do you see, can you tell me what was happening with the PH level and what did you do?

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF PUERTO RICO

CARLOS A. GARCIA PEREZ,	-	
GISELA M. BAERGA TORRES,	-	CIVIL NO. 97-1703
ET AL.	-	
Plaintiff	-	
vs.	-	
ALVARO SANTAELLA, M.D.;	-	
NEONATOLOGY GROUP OF	-	
ASHFORD PRESBYTERIAN	-	
COMMUNITY HOSPITAL,	-	
ET ALS.; ASHFORD PRESBYTERIAN	-	
COMMUNITY HOSPITAL, ET AL.	-	
Defendant	-	

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Deposition of:

IVAN TERON

taken on April 17, 2002, at the offices of Nachman, Guillemard and Rebollo, located at the San José Building, 9th Floor, Ponce de León, Santurce, Puerto Rico.

both not neonatologists, why she would be in a different situation than you regarding supervision?

MR. JOSE HECTOR VIVAS: Objection.

A I don´t know why she´d say that. I would simply be given my shift with specifications for the day given by the neonatologist and if I encountered any problems, I´d call the neonatologist.

Q Doctor Terón, you also testified that there was a daily plan that you received when you came on duty and that plan included monitoring the oxygen saturation level, so that it would not go below 90, is that... do you recall that?

A I don´t remember having stated it that way. I do remember that there were certain deliveries and there they'd tell me how the latest gases or arterial for the babies had flowed. And then it would indicate to lower the parameters for ventilation.

Q Was there a set policy not to have the saturation level not to go below 90?

A Well, the ideal would be that it not go below level of 90 and, in that case, the monitors would ring off.

Q O.K. The monitor was that on the oxygen meter machine?

A Yes, in the oxygen machine. Oxymeter.

Q O.K., so the alarm would off if the oxygen level went below 90. Would it also go off if the oxygen level went

above a certain number?

MR. JOSE HECTOR VIVAS: I have an objection as to the translation. Would not be "si la máquina se disparaba", si la alarma se disparaba".

THE INTERPRETER: I stand corrected.

THE DEPONENT: No, the alarm would only go off if it went below 90.

BY JOAN PETERS, ESQ.:

Q So, the nurses who were observing the oxymeter machine. That is what they would look for, whether, if the alarm went off and the level went below 90, that´s where their concern would be?

MR. JOSE HECTOR VIVAS: I have an objection to the form.

DEPONENT: I don't understand the question.

BY MS. JOAN PETERS:

Q The alarm goes off if the oxygen level goes below 90, is that correct?

A Yes.

Q Is it the nurses that are monitoring the alarm and the oxymeter machine?

A The nurses are the ones that place the monitor and, if the alarm goes off, they are the ones who verify if it is oxygenating. Whether the baby is moving, what´s happening.

Q Who is watching to see if the oxygen level goes too

A It is used as DID treatment. And also to transfuse platelets if they decrease a lot.

Q Besides the sepsis, do you think there was any other cause for the DID?

A No, it was the sepsis and on the previous day they indicated that an organism had been growing in the patient´s cephaloraquidio liquid. So, therefore, the patient did have sepsis and this entails a DID.

Q And, if you did keep, don´t lose this place where you are in the progress notes, but if you could also take a look at page 655?

A We are here.

Q O.K. Can you tell me about the baby´s PH level during this time period, 5-12 and 5-13?

A Yes, it says 7.17 at 8:00 a.m. Do you want them all or what is it that you want?

Q Looking at the PH levels for 5-12 during your 24-hour shift, 5-12 and 5-13, were those levels normal or abnormal?

A They were low.

Q What was being done to try to raise them?

A At 8:00 a.m. they began to administer sodium bicarbonate. That´s an order written by Doctor Santaella.

Q What was also being done regarding the parameters while the PH level was low?

A As far as the parameters for the ventilators, what the patient did have was a metabolic acidosis. And, what was needed to be done was to administer bicarbonate or to hydrate him plus during that period when the PH was low the patient was being transfused for blood and plasma.

However, notwithstanding by 2:00 p.m. in the afternoon, I began to lower the respiratory rate to try to compensate by creating an alcalosis, however, it was not attained. At that same hour bicarbonate was administered and in between the patient was transfused with plasma.

Q Would you agree that the standard care when you have an abnormal PH level as well as a low PCO2´s, that you would deal with the, and try to raise the PH level first before attempting to deal with the low PCO2´s?

MR. JOSE HECTOR VIVAS: I have an objection as to the question. An opinion is requested from the doctor regarding the standard of care and he is not here as an expert witness. He is here to testify as to his treatment. So, we object to the question.

MS. JOAN PETERS: O.K.

MR. JOSE HECTOR VIVAS: That regards to the question as presented and instructed not to answer.

MS. JOAN PETERS: You are instructing him not to answer?

MR. JOSE HECTOR VIVAS: The question as posted.